K082458

OCT 17 2008

510(K) SUMMARY

OFFICIAL CONTACT: Lisa M. Casavant
Sr. Regulatory Affairs Specialist
MEDRAD, Inc.
One MEDRAD Drive
Indianola, PA 15051
(412) 767-2400 ext. 3694

CLASSIFICATION NAME: Injector with Syringe, Angiographic

COMMON NAME(S): Powered Injector with Syringe (Accessory)

PROPRIETARY NAME: P3T™ Abdomen

PREDICATE DEVICES: MEDRAD Stellant CT Injector System with P3T™ CardiacFlow (K072886)

INTENDED USE: P3T™ Abdomen automates the calculation of individual contrast injection protocols, based on patient characteristics and contrast concentration. P3T™ Abdomen is a software application for use on a laptop computer.

INDICATIONS FOR USE: P3T™ Abdomen is indicated for use with CT angiography of abdominal organs (i.e., liver, pancreas, kidneys).

DEVICE DESCRIPTION AND COMPARISON TO PREDICATE:
Similar to the predicate device, P3T™ Abdomen automates the calculation of individual contrast injection protocols for CT imaging, based on patient characteristics and contrast concentration. Different from the predicate device, P3T™ Abdomen is intended for imaging of the abdominal region and operates on a laptop computer in the control room.

The Stellant Injector System operating software has not been modified for P3T™ Abdomen. The injector system, when used in conjunction with the P3T™ Abdomen laptop computer application, maintains the same intended use, same operational parameters, and same labeling. Every protocol generated by the P3T™ Abdomen laptop application must be manually entered into the injector. The Stellant Injector System user interface has not been modified for P3T Abdomen. The injector continues to enable modification or deletion of the protocol, and requires the user to approve and lock the protocol prior to injection. The practitioner always has the option of modifying or deleting the P3T™ Abdomen computed protocol.

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A comparison of features and principles of operation between the proposed device and predicate device is provided in Table 1.

Table 1: Comparison of P3T™ Abdomen Laptop Computer Application to P3T CardiacFlow on Stellant CT Injector System (K072886)

Feature	**Proposed Device: P3T™ Abdomen**	**Predicate Device: P3T™ CardiacFlow on Stellant CT Injector System (K072886)**
Intended Use	P3T™ Abdomen automates the calculation of individual contrast injection protocols, based on patient characteristics and contrast concentration. P3T™ Abdomen is a software application for use on a laptop computer. P3T™ Abdomen is indicated for use with CT angiography of abdominal organs (i.e., liver, pancreas, kidneys).	The P3T™ CardiacFlow software computes individual contrast injection protocols and scan timing, based on patient characteristics, scanner parameters and contrast concentration. The P3T™ CardiacFlow software is intended for use in CT angiography of cardiac structures, including coronary arteries, chambers of the heart, and thoracic and abdominal aorta during gated ECG acquisition.
Location of Application	The P3T™ Abdomen software runs on a laptop computer in the control room, and has no impact on the operation of the Stellant Injector. The user will continue to be required to confirm the protocol entered into the injector before beginning an injection.	The P3T™ CardiacFlow software is contained within the Stellant Injector operating software. The P3T ™ CardiacFlow software can be turned on or off by the user for any given injection. The user will be required to confirm the suggested protocol before beginning an injection.
Dosing method	P3T™ Abdomen allows the user to select from three dosing methods.	P3T™ CardiacFlow has a predetermined dosing method.
Flow Rate Limiting	P3T™ Abdomen prevents the user from setting a flow rate or	If P3T™ CardiacFlow calculates a flow rate that exceeds the preset

Feature	Proposed Device: P3T™ Abdomen	Predicate Device: P3T™ CardiacFlow on Stellant CT Injector System (K072886)
	injection duration value that would cause result in a flow rate that exceeds the preset maximum flow rate.	maximum flow rate, it modifies (reduces) the flow rate.
Delivery Programming	P3T™ Abdomen allows the user to enter a flow rate or to create a protocol based on injection duration.	P3T™ CardiacFlow creates a protocol based on flow rate.
Number of Phases	P3T™ Abdomen enables three phases, a test inject phase and two diagnostic phases (contrast and saline flush).	P3T™ CardiacFlow enables up to seven phases including a test inject phase, test bolus phase, and multiple diagnostic phases.
DualFlow Functionality	P3T™ Abdomen does not support DualFlow functionality.	P3T™ CardiacFlow implements DualFlow functionality (phases with simultaneous injection of contrast and saline).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2008

MEDRAD, INC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K082458
Trade/Device Name: P3T™ Abdomen
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK, DXT
Dated: October 6, 2008
Received: October 7, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082458

Device Name: P3T™ Abdomen

Indications for Use:
P3T™ Abdomen automates the calculation of individual contrast injection protocols, based on patient characteristics and contrast concentration. P3T™ Abdomen is a software application for use on a laptop computer.

P3T™ Abdomen is indicated for use with CT angiography of abdominal organs (i.e., liver, pancreas, kidneys).

Contraindications (if applicable): None

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082458